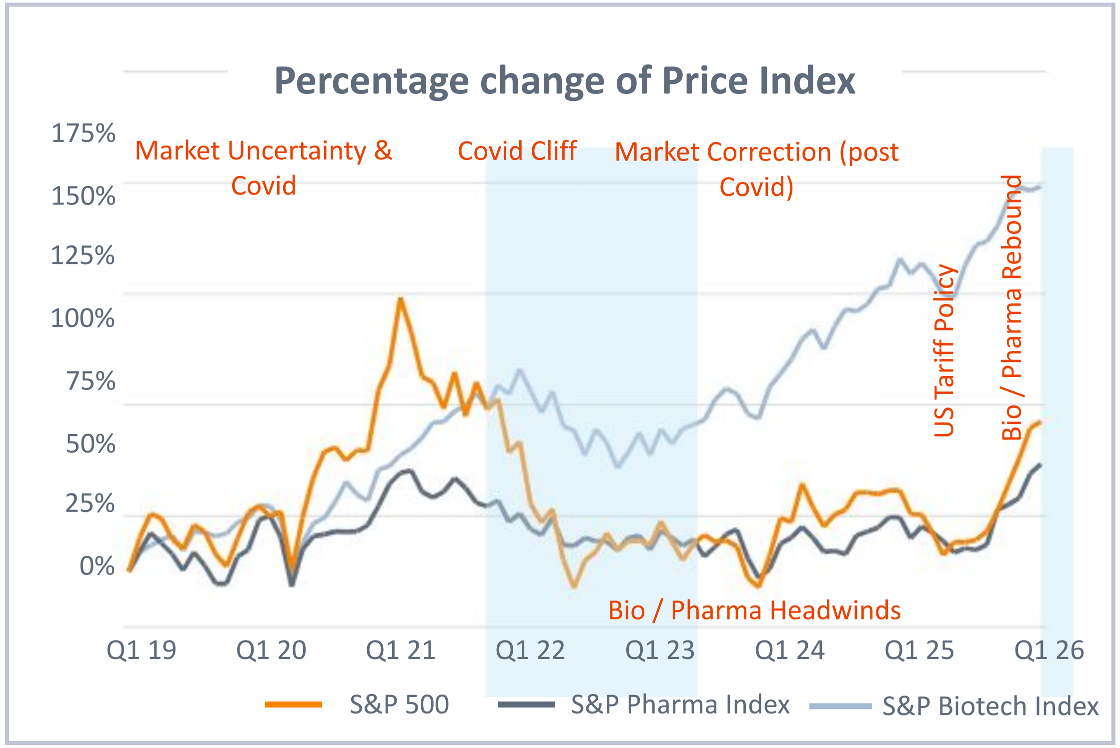
Inside the Advanced Therapies CDMO Landscape

Prof. Daniel C. Smith, PhD.
Nice Insight & Consulting

State of the Industry: The New Normal

- Ongoing economic & geopolitical tensions continue to create market uncertainties
- Investment did not rebound in 2025; markets remain risk-averse
- Innovation cannot wait for macro conditions to improve
- Companies must make progress within today’s constraints
- Progress depends on acceptance of this “new normal”



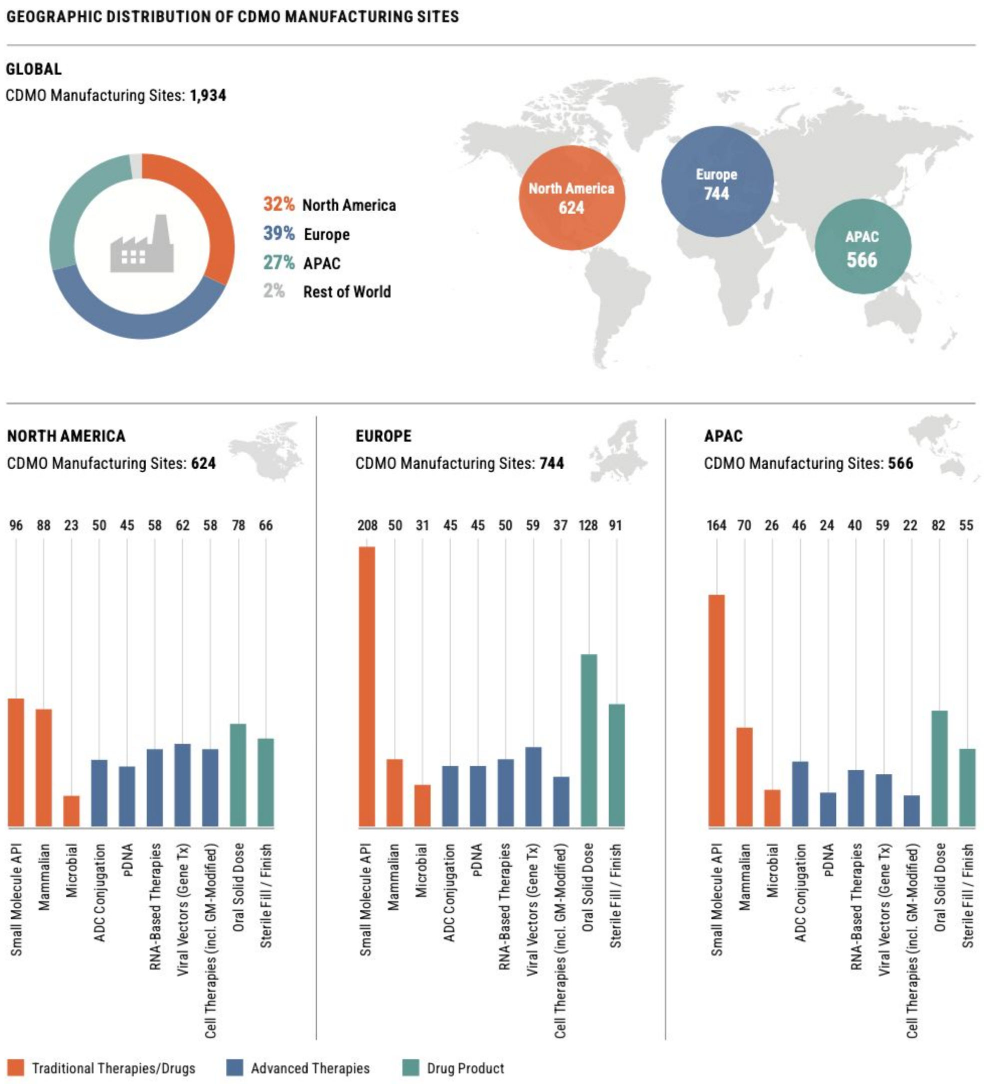
Data source: S&P Dow Jones Indices LLC; Data analysis Nice Insights

The Global CDMO “Metaverse”

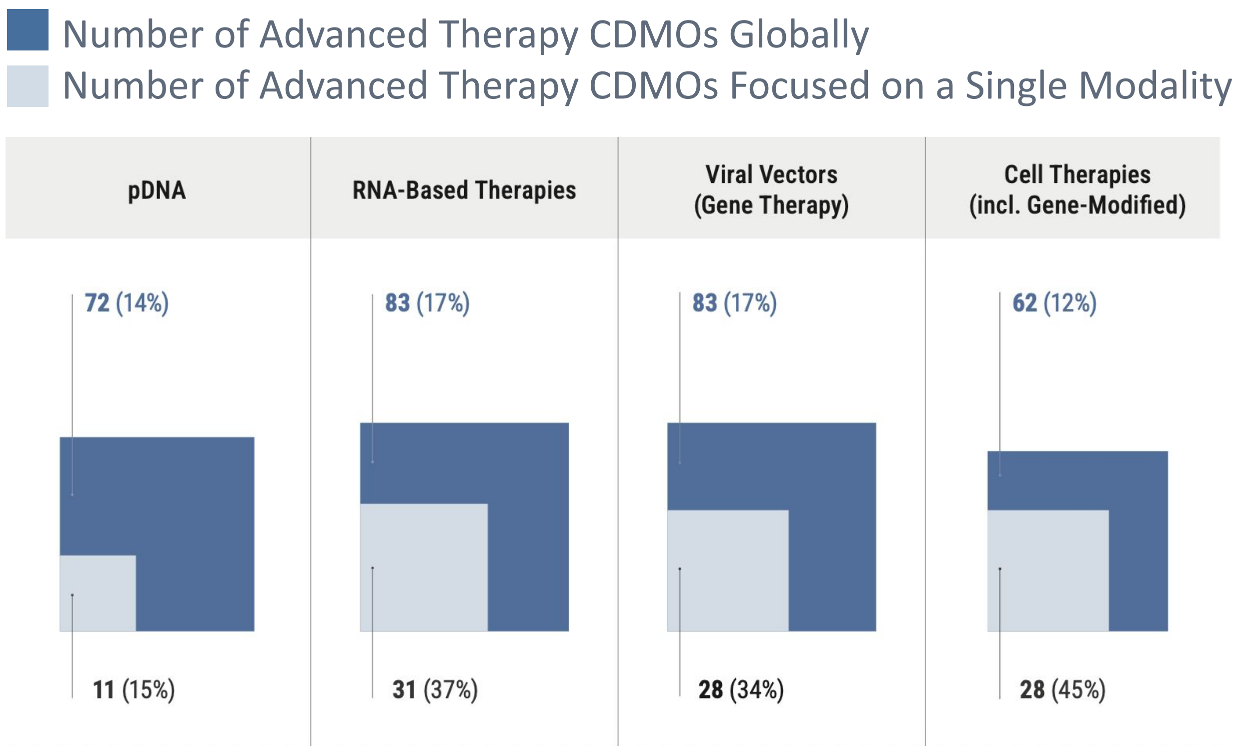
THE GLOBAL CDMO “METAVERSE”

Total number and percentage of CDMOs per modality, and number and percentage of which focus on a single modality.

Traditional Therapies/Drugs
Single-Focus Traditional Therapies/Drugs CDMO
Drug Product CDMO capability
Single-Focus Drug Product CDMO capability
Advanced Therapies
Single-Focus Advanced Therapies



The Advanced Therapies CDMO Landscape

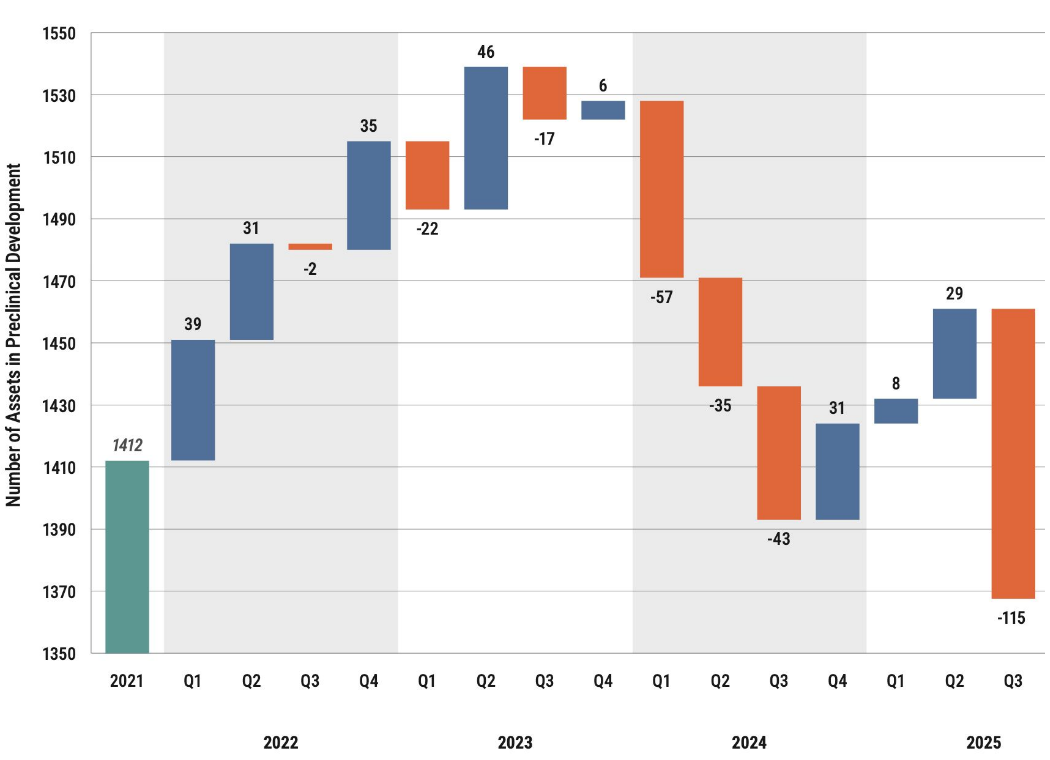


- Most advanced therapy CDMOs are in North America (40%), then Europe (34%), with only 26% in APAC
- A high degree of specialism within the advanced therapies manufacturing market
- 45% of CDMOs focus solely on cell therapy manufacture
- Compared to plasmid manufacturing CDMOs; 15% of which focus solely on pDNA

CGT Preclinical Pipeline Demonstrates Headwinds

- Headwinds felt in the CGT CDMO sector in 2023-24 are still blowing
- Preclinical pipeline showed signs of recovery Q4 2024 – Q2 2025
- Q3 2025 saw a significant decrease, resulting in the lowest number of pre-clinical assets in development since mid 2021
- 2025 ended with a further decrease of 119 pre-clinical assets (not shown); ↓20% from 2023 peak
- State of the preclinical pipeline will inevitably impact the number of clinical projects that translate to requiring CDMO services in 2026

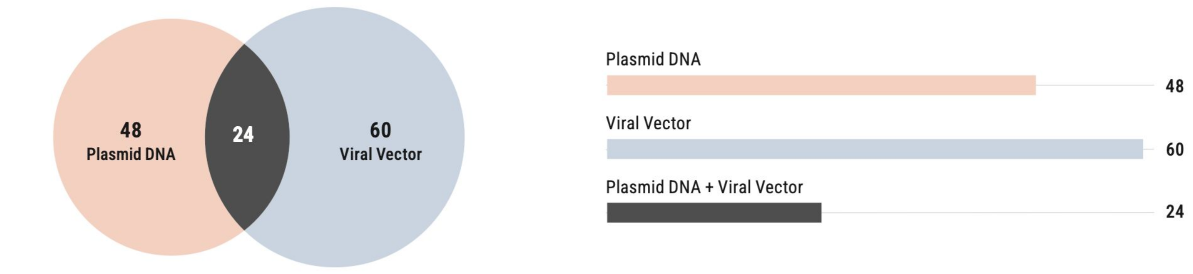
EVOLUTION OF THE CELL AND GENE THERAPY PRECLINICAL PIPELINE (2022-2025)



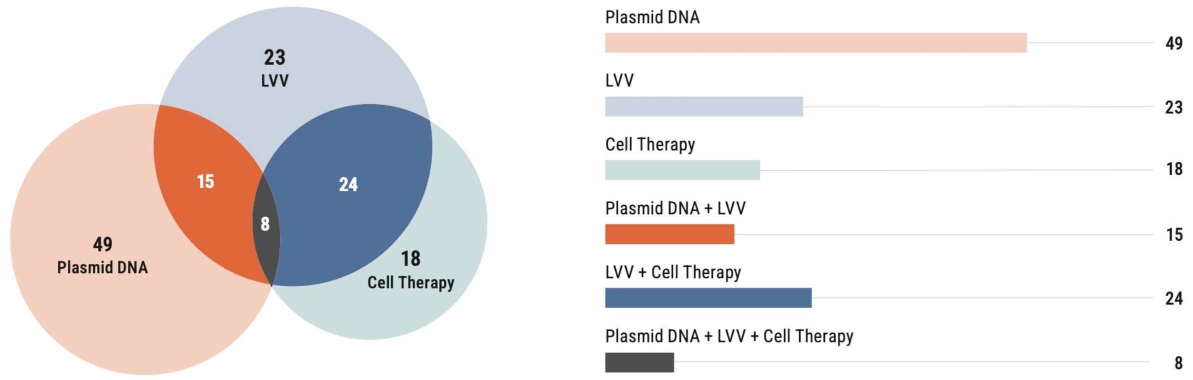
Data source: ASCGT Quarterly reports; Data Analysis Nice Insights

Competitive Landscape Influences CDMO Positioning

SUPPLY CHAIN INTEGRATION FOR *IN VIVO* GENE THERAPY



SUPPLY CHAIN INTEGRATION FOR *EX VIVO* GENE THERAPY

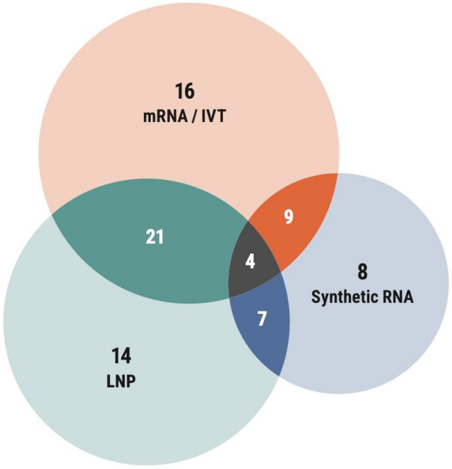


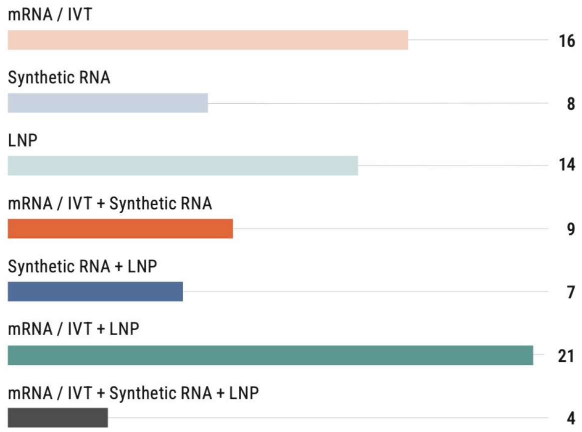
- Increased competition for clinical & commercial projects has led to a shift in positioning
- 2022-2024 saw CDMOs differentiate and build resilience by establishing integrated services across the supply chain
- With nearly 40% integration within the "*In Vivo* Gene Therapy" CDMO supply chain

- 2025 saw the number of "specialized" CDMOs increase, offering clear differentiation from the "integrated" competition (↓18%)
- Clients demanding deep modality-specific expertise and industry-leading technologies

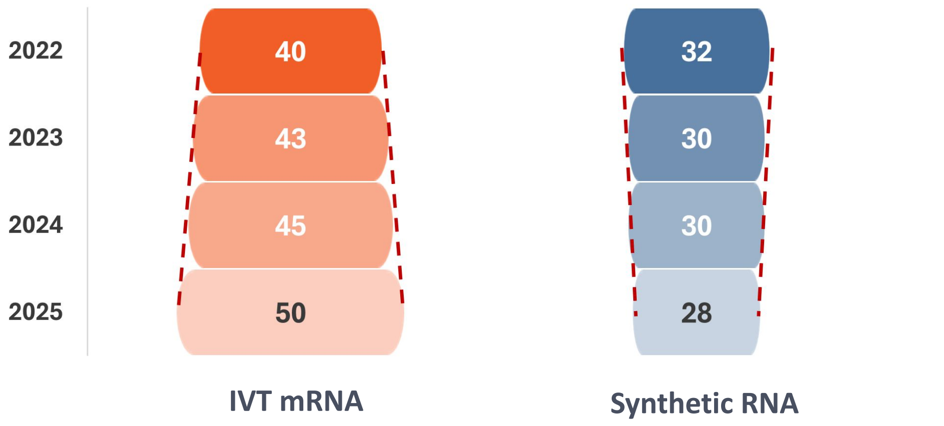
The Advanced Therapies CDMO Landscape (RNA)

- By the end of 2025, 79 CDMOs globally offered RNA/LNP production capability across 148 sites
- North America has the most (39%), then Europe (34%), and APAC (27%)
- There is a high degree of specialism (48%) within the RNA/LNP CDMO landscape
- By the end of 2025, 74% of RNA CDMOs had dedicated IVT mRNA/LNP production capability
- Post-COVID saw a 14% increase in the expansion/addition of IVT mRNA CDMO capability and capacity
- The number of CDMOs offering synthetic RNA production has remained relatively stable

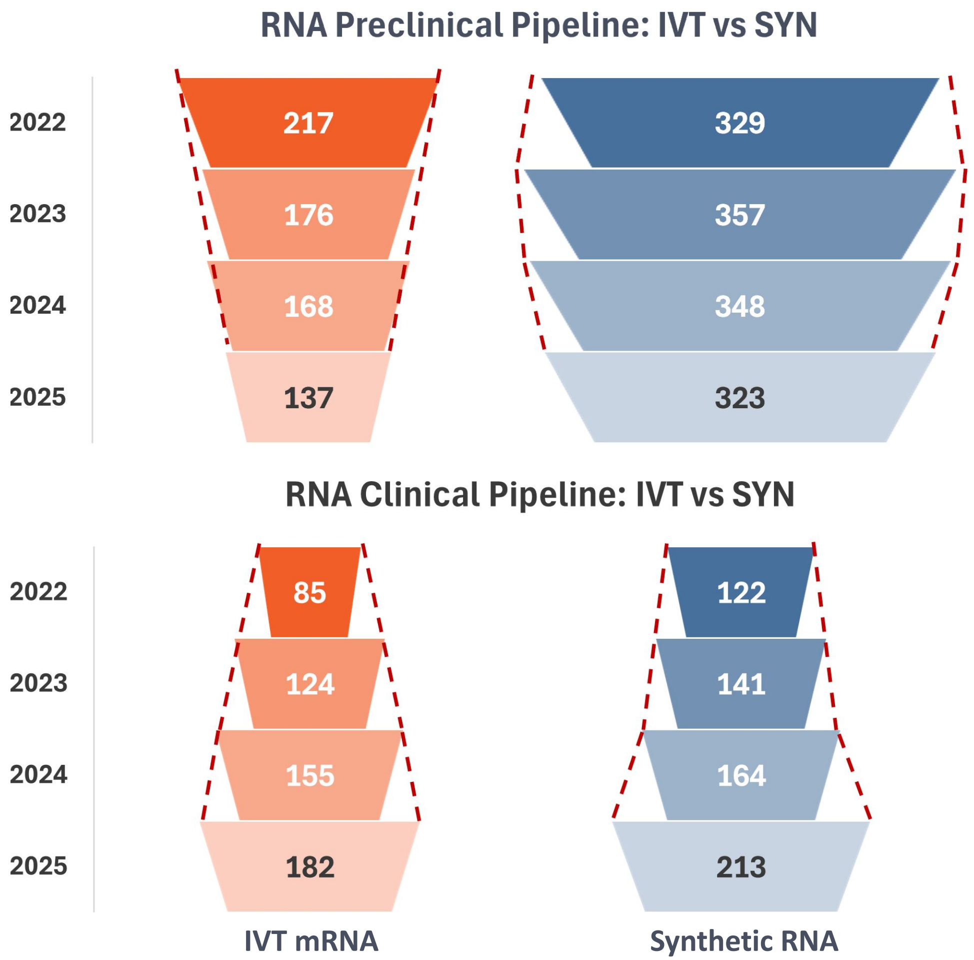




RNA CDMO Landscape: CDMOs with IVT vs Synthetic RNA production



Specialist Focus is a Disadvantage for IVT-based mRNA CDMOs



- All mRNA approvals are vaccines; they tend not to be outsourced and produced at a scale not supported by most of the CDMOs
- The mRNA pre-clinical & clinical pipelines have not yet proved strong enough to support the level of IVT/mRNA CDMO capacity

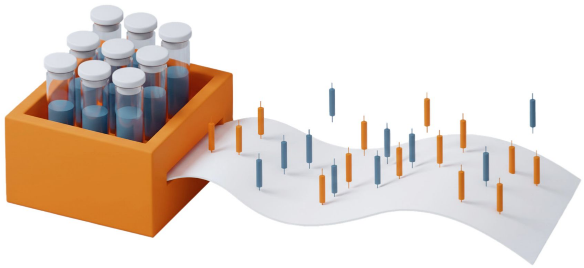
RNA pipeline supports Synthetic RNA production

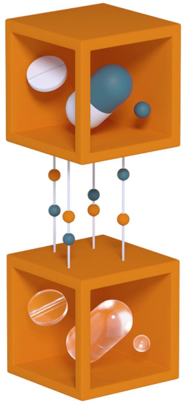
	Assets per CDMO		
	IVT	SYN	Fold
Preclinical	3	12	4
Clinical	4	8	2
Total Pipeline	7	20	3

- IVT CDMOs that have not diversified or been supported by a diversified parent organization have struggled

Technology Differentiation in the CGT CDMO Sector

- Technology is no longer an enabler for advanced therapies CDMOs, it's the defining edge
- Automation, digital twins & AI-driven analytics are transforming complex processes into scalable systems
- In cell therapy manufacturing, a new generation of closed, automated systems is reaching commercial readiness
- Synthetic DNA is becoming a mainstream enabler for gene therapy, gene editing, and mRNA platforms





Increased Competition Influences Pricing Dynamics

- 2024-25 saw more clients requesting smaller, exploratory projects for early-phase gene therapy
- Platform feasibility and manufacturability assessment priced between $50,000 and $190,000, depending on scale
- GMP batch LIST pricing for mid to late clinical stage remained relatively stable over 2024-2025, with no geographic variability in pricing observed
- Actual batch prices were driven by the need to win business and to support client fundraising, in the hope of later-phase retention
- CDMOs that could afford to do so performed IND-enabling work for free, on a delayed-payment basis, or in exchange for equity

Regulatory Flexibility Elevates the Role of CDMOs

- FDA regulatory flexibility for cell and gene therapies is a clarification, not deregulation
- Misinterpreting flexibility as reduced oversight risks undermining confidence in the CGT sector as a whole
- Strong emphasis on phase-appropriate CMC controls without reducing expectations for safety, purity, or potency
- Critical technology enablers of flexibility are automation, closed systems, and PAT, supporting phase-appropriate control in CGT manufacturing
- CDMOs have a critical strategic role, as continuity anchors, to provide robust data-driven control and disciplined manufacturing execution, combined with compliant inspection readiness

FDA Increases Flexibility on Requirements for Cell and Gene Therapies to Advance Innovation

Winning the CGT CDMO Game in 2026

- The advanced therapies sector will remain a buyer's market for early clinical sponsors until investment returns
- CDMOs must strengthen strategic partnerships; shifting to long-term, collaborative partnerships that span early research through commercialization
- Differentiate through technical specialization, focus on niche capabilities rather than trying to be everything to everyone
- The "one-stop shop" narrative is giving way to "best-in-class within a network," where interoperability across trusted specialists replaces vertical integration
- Smart deployment of next-gen technologies will accelerate competitiveness

As we enter 2026, pricing power now stems from scarcity of expertise, specialized infrastructure, and regulatory mastery, not from scale alone."

Daniel Smith, Ph.D.
Chief Scientific Officer, That's Nice

DNA synthesis technologies from firms like Elegen and Touchlight are eliminating the plasmid bottleneck that constrains upstream processes, enabling shorter timelines, higher reproducibility, and simplified regulatory pathways for vector and mRNA programs."

Advanced Therapies Panel Opinion

An introduction to Nice Insight & Consulting

niceconsulting
Impact through Insight

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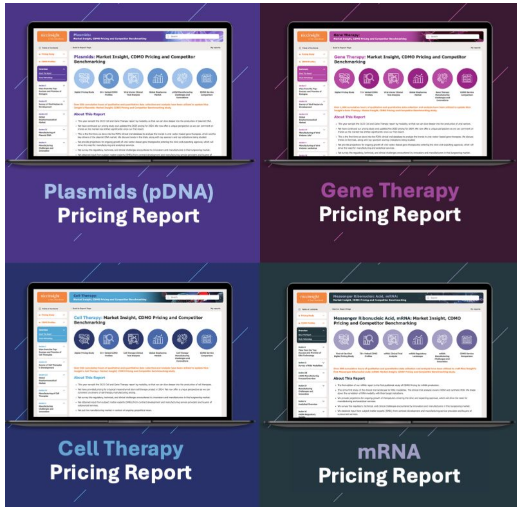
Market Research & Technology

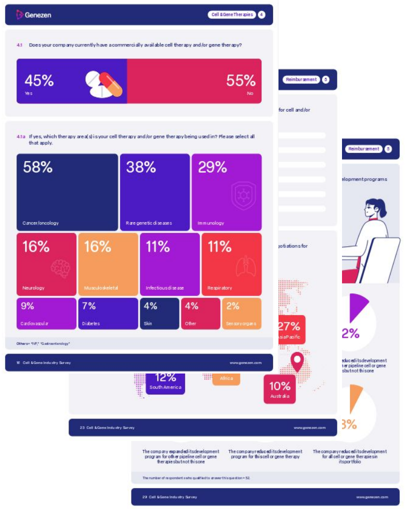
State of the Industry Report: 2026

- CDMO Landscape
- Trends & Opinions
- Industry KOL Input
- Pricing Dynamics



CDMO Pricing & Benchmarking Reports

- 502+ CDMOs Tracked
- Trends & Opinions
- Contact Mapping
- CDMO Database
- In-depth Clinical-to-Commercial RFP Pricing



Custom KOL Research Surveys

- Targeted Surveys
- Market Assessments
- Competitive Intelligence
- Contact Mapping
- Pricing Analysis

Market Demand Reports

- Evaluating New Markets
- Assessing Investment Trends
- Identifying Priority Customers
- Uncovering Adoption Barriers

Thank You

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